PRODUCT APPLICATION:
- PreferredOne Administrative Services, Inc. (PAS) ERISA
- PreferredOne Administrative Services, Inc. (PAS) Non-ERISA
- PreferredOne Community Health Plan (PCHP)
- PreferredOne Insurance Company (PIC) Individual
- PreferredOne Insurance Company (PIC) Large Group
- PreferredOne Insurance Company (PIC) Small Group

PURPOSE:
The intent of the Rituxan Prior Authorization criteria document is to ensure that the intended use is medically necessary and prescribed after conservative treatment has failed.

GUIDELINES:
Medical Necessity Criteria – Must satisfy one of the following: I or II

I. Rituxan is requested for one of the following FDA approved indications: A-D

   A. Granulomatosis with Polyangiitis (GPA) (Wegener’s Granulomatosis) or Microscopic Polyangiitis (MPA) – must satisfy one of the following: 1 or 2
      1. Allow if the member is currently taking the medication; or
      2. If the member is not currently taking the medication, assess disease characteristics – must satisfy one of the following: a or b
         a. Allow for members with mild disease (ie, normal serum creatinine and no red cell casts or proteinuria) and no organ-threatening or life-threatening manifestations (ie, absence of pulmonary hemorrhage, cerebral vasculitis, progressive neuropathy, orbital pseudotumor, GI bleeding, pericarditis or myocarditis) after failure of glucocorticoids in combination with methotrexate; or
         b. Allow for members with moderate to severe disease (ie, organ-threatening or life-threatening manifestations including, but not limited to, marked pulmonary or rapidly deteriorating renal function).

   B. Oncology Diagnoses: See National Comprehensive Cancer Network (NCCN) Guidelines

   C. Pemphigus vulgaris and other autoimmune blistering skin diseases – must satisfy one of the following: 1-2
      1. After failure of glucocorticoids or unacceptable side effects develop from long-term use of glucocorticoids; or
      2. After failure of immunosuppressive drugs (such as, but not limited to, azathioprine, cyclophosphamide, or mycophenolate) in combination with glucocorticoids as adjuvant therapy.

   D. Rheumatoid Arthritis: See criteria PC/B004 Biologics for Rheumatoid Arthritis
II. Rituxan is allowed for one of the following off-label diagnoses if the member is currently taking the medication. If not currently taking the medication – must satisfy one of the following: A-P

A. Autoimmune hemolytic anemia (AIHA) warm agglutinins (positive direct Coombs test) – must satisfy both of the following: 1 and 2
   1. After failure of, inability to tolerate, or necessity for higher maintenance dose (greater than 15 to 20mg per day) of glucocorticoids; and
   2. After failure of immunosuppressive drugs (such as, but not limited to, azathioprine, or cyclosporine).

B. Cryoglobulinemia – refractory to glucocorticoids and other immunosuppressive agents

C. Dermatomyositis or polymyositis - after failure of glucocorticoids plus either azathioprine or methotrexate

D. Graft versus host disease (GVHD), chronic – refractory to other treatments (last resort treatment)

E. Heart transplant rejection, antibody mediated – prevention of recurrence

F. Idiopathic membranous nephropathy (IMN) - hemolytic uremic syndrome [HUS], resistant – must satisfy all of the following: 1-3
   1. Moderate- or high-risk member; and
   2. Presence of stable renal function; and
   3. After failure of both cyclophosphamide and calcineurin inhibitor-based regimens.

G. Idiopathic thromboeytopenic purpura (IPP) – after failure of glucocorticoids

H. Lupus nephritis, refractory – after failure of, or inability to tolerate both cyclophosphamide and mycophenolate mofetil (MMF)

I. Membranous glomerulonephropathy (MGM) – after failure of glucocorticoids or other immunosuppressants

J. Multicentric Castleman’s disease (MCD) – following disease stabilization with chemotherapy

K. Neuromyelitis Optica (NMO) – after failure of one or more immunosuppressants

L. Post- organ transplant CD20 positive lymphoproliferative disorder (PTLD)

M. Pre-renal transplant in individuals with high panel reactive antibody levels to suppress panel reactive anti-HLA (human leukocyte antigen) antibodies

N. Sjogren’s syndrome, in individuals with extraglandular manifestations, eg, brain, gastrointestinal tract, heart, joints and muscles, kidneys, liver, lungs, lymph nodes and bone marrow (lymphoma), bladder, pancreas, peripheral nervous system, skin, thyroid gland - refractory to glucocorticoids and other immunosuppressive agents
O. Thrombotic thrombocytopenic purpura (TTP), relapsed or refractory – must satisfy 1 and any of the following: 2-4
   1. Member has a more severe or prolonged clinical course; and
   2. Member has relapsing disease; or
   3. After failure of plasma exchange alone; or
   4. After failure of plasma exchange plus glucocorticoids.

P. Waldenstrom macroglobulinemia – must satisfy either of the following: 1 or 2
   1. Low tumor burden and/or minimally symptomatic disease; or
   2. Severe symptoms in combination with chemotherapy.

[Note: Rituxan is only for adults greater than or equal to 18 years of age.]

EXCLUSIONS:
Rituxan for all other indications not covered above is considered investigative (see Pharmacy Investigative List).

DEFINITIONS:
B-cells:
A white blood cell specially designed to be responsible for the body’s immunity

CD20:
A non-glycosylated phosphoprotein expressed on the surface of all mature B-cells

BACKGROUND:
This criteria document is based on U.S. Food and Drug Administration (FDA) approved indications and dosing, expert consensus opinion and/or available reliable evidence.
FOR INTERNAL USE ONLY

COVERAGE:
Prior Authorization: Yes

Coverage is subject to the member’s contract benefits.

CODING:
HCPCS
J9310 Injection, rituximab, 100mg (Rituxan)

Coverage is subject to the terms of a member’s benefit plan. To the extent there is any inconsistency between
this criteria document or policy and the terms of a member’s benefit plan, the member’s benefit plan govern.

Approval of a drug under this criteria document does not ensure full coverage of the drug.

RELATED CRITERIA/POLICIES:
Pharmacy Criteria: PC/B004 Biologics for Rheumatoid Arthritis

REFERENCES:


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PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan ("PCHP") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN  55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)


Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).


注意：如果您使用繁體中文，您可以免費獲得語言援助服務，請致電1.800.940.5049 (TTY: 763.847.4013).

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).


Languages: Available for services in English, Spanish, Chinese, and many other languages.

ATTENTION: Si vous parlez français, des services d’aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013)으로 전화해 주십시오.


NDR PCHP LV (10/16)
PreferredOne Insurance Company Nondiscrimination Notice

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• Qualified sign language interpreters
• Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:
• Qualified interpreters
• Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)


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โปรดทราบ: หากคุณพูดภาษาไทย คุณสามารถขอรับการให้บริการช่วยเหลือได้ฟรีที่ 1.800.940.5049 (TTY: 763.847.4013).


МЕЛЛОЗА: Если вы говорите на французском языке, вам предлагается бесплатные услуги перевода. Вы можете позвонить 1.800.940.5049 (TTY: 763.847.4013).

ATTENTION: Si vous parlez français, des services d’aide linguistique vous sont proposés gratuitement. Appelz le 1.800.940.5049 (TTY: 763.847.4013).

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PAUNAWA: Kung nagpasalita ka ng Tagalog, maaraa kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).